ISBT 128
For Human Milk

An Introduction

6th Edition - 2024

IN-031

Editor

Karen Moniz, MHA, MT(ASCP)SBB
Technical Director
ICCBBA

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Published by:
ICCBBA
PO Box 11309, San Bernardino, CA 92423-1309 USA
www.isbt128.org

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1 Preface

A great deal of important information is presented on the label of banked products of human milk origin. The information varies from country to country according to licensing regulations, language differences, and local practice, but, in all cases, it is essential that products are uniquely identified, and that product information is recorded accurately, transferred correctly, and that critical items such as the expiration date and product description are clearly understood by the person administering the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

Individuals dealing with the collection and administration of banked human milk must ensure the safety of the recipient by making certain the right product gets to the right recipient and that traceability records are accurately maintained. Transfer of information by electronic means enhances accuracy as well as adds efficiency to the process.

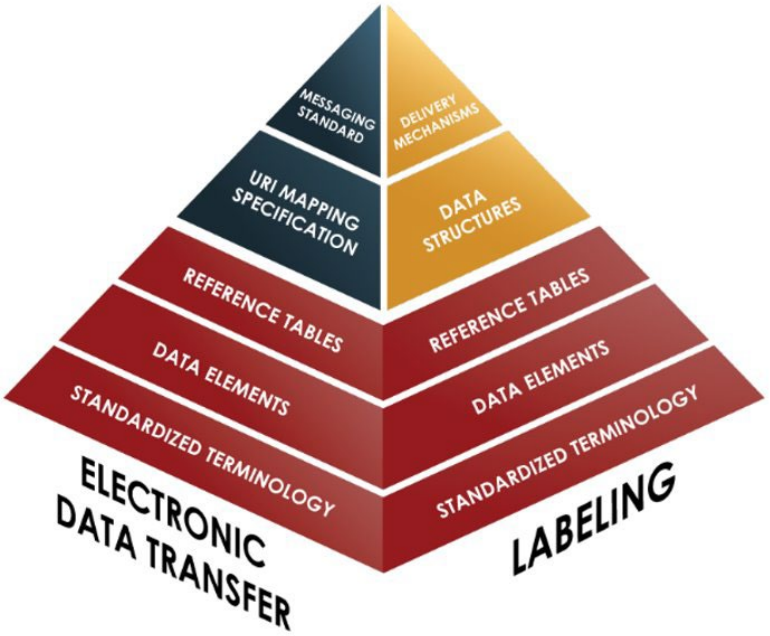
An editorial published in the Bulletin of the World Health Organization (WHO) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646341/) recognized the need for effective traceability of all medical products of human origin (MPHO), including blood, organs, bone marrow, cord blood, corneas, tissues, reproductive cells and milk, to ensure recipient safety and called for the global adoption of ISBT 128 as the coding system for all MPHO.

The development of ISBT 128 for human milk banking is being overseen by the Milk Banking Technical Advisory Group (MBTAG), supported by the European Milk Bank Association (EMBA) and the Human Milk Banking Association of North America (HMBANA). These organizations and ICCBBA have issued the *International Consensus Statement on the Terminology, Coding and Labeling of Human Milk Donations* (JP-006).

2 What is the Information Environment?

The information environment model describes how ISBT 128 organizes information to achieve standardization for both labeling and electronic messaging for medical products of human origin (MPHO).

The information environment consists of standardized terminology, data elements, and reference tables. These layers support the structures, mechanisms, specifications, and standards necessary to print labels and create electronic messages. These layers are modeled and described below:



Standardized Terminology

At the base of the information environment lies the standardized terminology, *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002), that helps ensure a common understanding of terms. Standardized terminology is used for both labeling and electronic messaging. Without clarity at this level, any further attempt at standardization would be unsuccessful. Obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus.

A simple example serves to illustrate this. While the term 'pasteurized' is defined as heating a liquid to a specific temperature, different national guidelines may exist to achieve this process, therefore, the definition of the **Pasteurized** attribute states that the product has been pasteurized in accordance with national guidelines.

ICCBBA ensures that internationally agreed-upon standardized terminology is defined at the required level of granularity. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology is accessible to all users of the ISBT 128 Standard and stakeholders.

Data Elements

Product information and characteristics such as the Donation Identification Number, Expiration Date and Time, and Product Description Code constitute a data element. Data elements can be encoded within data structures suitable for use in bar codes and they can be used in the electronic exchange of information. In some instances, more than one data element is encoded in a data structure.

Example: The Product Code data structure contains up to 3 data elements: the Product Description Code, the Collection Type Code, and the Division Identifier.

Reference Tables

Reference tables are built to code/decode data elements to provide data compression for use in a data structure. Such tables can be large and complex, and they are managed to ensure that they can be modified to meet changes within clinical practices in a manner that maintains their integrity and avoids ambiguity or redundancy.

Successful management of standardized terminology, data elements, and reference tables requires input from both clinical experts in the field and information specialists. The reference tables are published in a manner that allows all users of the Standard to access up-to-date versions.

Together, the standardized terminology, data elements, and reference tables provide the basis for accurately relaying information about medical products of human origin, whether on the label or via electronic data transfer.

Electronic Data Transfer

The development of a standardized approach to incorporate ISBT 128 data elements into electronic messages is an important step in improving communication between healthcare organizations involved in the production and clinical application of MPHO.

URI Mapping Specification for Use in Electronic Messaging

To support the transmission of ISBT 128 information via electronic messaging, ICCBBA has developed a dictionary of data elements, *ISBT 128 Dictionary of Standard Data Elements* (ST-027). Please refer to this document for additional information.

To view an example of a Product Description Code data element, go to https://www.isbt128.org/uri/ProductDescriptionCode.

Messaging Standard for Use in Electronic Messaging

The *ISBT 128 Standard for XML Electronic Messaging - Standardized XML Elements for Medical Products of Human Origin* (ST-020) provides specifications for use in electronic messages to convey information regarding MPHO in a consistent and standardized format.

The MPHO Unique Identifier is a single unique instance identifier developed to provide the basic elements of traceability. This identifier can be created from a standard ISBT 128 label and uniquely identifies the specific product being referenced in an electronic message. Specifications for the MPHO Unique Identifier are detailed in the *ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier* (ST-026).

Labeling

Data Structures for Use in Labeling

Having built reference tables that convert the clearly defined information into codes suitable for use in bar codes applied to product labels, it is necessary to define data structures in which to embed the product data. Data structures define the technical characteristics necessary for the interpretation of information. They specify the context and structure and provide the links to the appropriate reference tables for the conversion of codes to meaningful information.

Data structures must be unambiguous and consider any constraints imposed by the anticipated delivery mechanisms. For example, data structures that will be used in linear bar codes are limited in the number of characters they can contain.

Data identifiers indicate the type of information being conveyed within data structures. The appropriate data identifiers must be used for each data structure to ensure the correct interpretation of the encoded information.

Delivery Mechanisms for Use in Labeling

The delivery mechanism is the means of delivering electronic information encoded within data structures. The most well-known delivery mechanism is the linear bar code that has been used in blood transfusion practice for many years.

Higher capacity delivery systems are available using Data Matrix two-dimensional (2-D) or reduced space symbology bar codes. These codes can carry much more information in each symbol. More recently, the use of Radio Frequency Identification (RFID) chips that can carry encoded information is being implemented for some medical products of human origin.

A range of delivery systems can exist at this level of the hierarchy. The standardized terminology, reference tables, and data structures of the information standard can be encoded as easily in a linear bar code as they can in an RFID tag. The standards themselves must be adaptable in order to make the best use of new delivery mechanisms, such as Bluetooth Low Energy (BLE) tags or micro-electromechanical systems (MEMS) as they are developed.

Information Environment Summary

Every ISBT 128-labeled product carries a standardized label where product information is encoded in bar codes or electronic tags. Although there will be other labeling requirements that fall outside the coding system, an effective coding system should consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, there needs to be a mechanism that will ensure the correct physical assignment of information to the product, and confidence in the association between electronically stored information and eye-readable printed information.

This requirement must not be overlooked in the enthusiasm to embrace remotely rewriteable tags.

While highly effective and secure, labeling does have some limitations. In particular, the amount of information that can be encoded on the label depends on the amount of label space available to accommodate bar codes.

The information environment layers work together to ensure standardization of the information encoded within an electronic message or label. This facilitates accurate data interpretation and interoperability across different information systems and healthcare settings. For such a system to be and to remain effective, it must be carefully designed and managed. The ICCBBA Technical Advisory Groups support an ongoing dialogue between clinicians, information specialists, and equipment and software vendors to ensure that the Standard continues to support rapidly developing clinical practices, ensures traceability, improves biovigilance records, and increases patient safety.

3 The ISBT 128 Standard

The ISBT 128 Standard provides the specification for many of the elements of the information environment required in product administration. It defines the lower three levels of the model: the standardized terminology, reference tables, and data structures. Minimum requirements are also defined for delivery mechanisms and labeling. By complying with ISBT 128, collection and processing facilities can provide electronically readable information that can be read by any other compliant system.

The ISBT 128 Standard specifies:

- a donation numbering system that ensures globally unique identification for a one-hundred-year period;
- the information to be transferred, using internationally agreed reference tables;
- an international product reference database;
- the data structures in which this information is placed;
- a barcoding system for the transfer of the information on the product label;
- a standard layout for the product label;
- a standard reference for use in electronic messaging.

The Standard, originally designed for use in blood transfusion, has been expanded and developed over time to accommodate the adapting needs of various MPHO industries. This inherent elasticity of the Standard has led to its international acceptance and widespread use for labeling of MPHO products, with more than 40 million MPHO products labeled using ISBT 128 each year.

The most current version of the standard terminology is maintained on the ICCBBA website at https://www.isbt128.org/standard-terminology.

4 Unique Donation Identification

ISBT 128 provides for the unique identification of any donation worldwide. It does this by using a 13-character identifier built up from three elements, the first identifying the collection facility, the second the year, and the third a sequence number for the collection. For example:

G222024600002 00 **Y**

where:

G2220 identifies the Facility Identification Number of the collection facility (in this case NHS GGC Scotland Wide Donor Milk Bank);

24 identifies the year in which the Donation Identification Number was assigned (i.e., 2024);

600002 is the sequence number of the collection assigned by the collection facility.

The two digits printed vertically allow individual bar codes in a number set to be discretely identified hence providing an option to add process control.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is entered into a computer system through the keyboard to verify the accuracy of the keyboard entry.

Facility Identification Numbers are assigned by ICCBBA who maintain a database of all registered facilities on their website (www.isbt128.org). A lookup program allows the lookup of individual facility codes. ICCBBA-licensed facilities and vendors can download a full listing of all registered facilities.

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product codes. The foundation of this system is standard terminology that is constructed by international consensus to ensure global consistency in use and understanding. The standard terminology is maintained on the ICCBBA website and is publicly available. Human milk terminology and coding are managed by ICCBBA and the international Milk Banking Technical Advisory Group (MBTAG), supported by the European Milk Bank Association (EMBA) and the Human Milk Banking Association of North America (HMBANA).

New products are defined by combining pieces of information from the standardized terminology in a way that unambiguously describes the product. This process is made easier by the use of the concepts of product class and attributes.

Each unique product description is assigned a Product Description Code that becomes incorporated into the ISBT 128 Product Description Codes table within the database, ensuring that the product will be accurately identified in any country in the world that is using the ISBT 128 Standard.

New entries into the ISBT 128 Product Description Code Database can be readily accommodated allowing the system to expand to meet a growing range of products without losing the overall structure of the coding system.

The following example is taken from the database table:

Component Class:	HUMAN MILK
Attributes:	<=-30C
	Pasteurized
	For nutritional use

Product Description Code: M0001

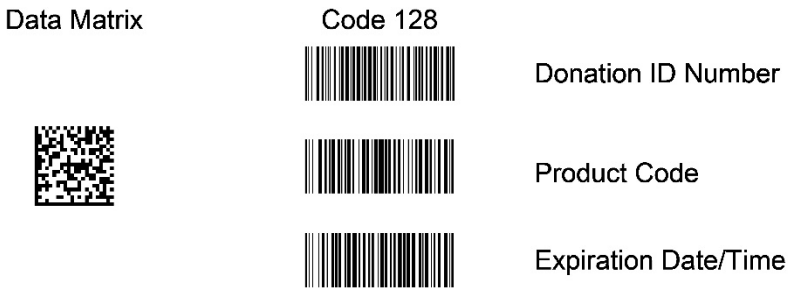
While the description of a product in the ISBT 128 Product Description Code Database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

6 Delivery Mechanisms

The delivery mechanism is the means by which the information is represented in a machine-readable manner. The most common such mechanism is the linear bar code. ISBT 128 has traditionally been based on the linear bar code using Code 128 symbology. However, a two-dimensional Data Matrix symbol can be used on labels for banked products of human milk origin and is preferable to maximize space on the label.

A single Data Matrix symbol can carry the same information as encoded in multiple linear bar codes. This allows much more rapid scanning of units at the point of milk bank issue and administration. Banked human milk often is stored in small containers which means that label size is severely restricted, and in these situations, a more efficient two-dimensional Data Matrix symbol can be used.

Comparative Size of a 2-D Data Matrix Symbol and Linear Bar Codes



The Data Matrix symbol on the left contains all of the information held in the three Code 128 symbols on the right.

There is also interest in the use of RFID tags. This technology may provide significant benefits in some situations. ISBT 128 compound messages are compatible with RFID.

7 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides requirements for information that shall appear on the final label for human milk products. Eye-readable information such as the Donation Identification Number and text of the Product Code are among the minimum elements required.

Since there is not a standard size container used for milk products, the ISBT 128 Standard does not specify a particular size of label. Additional nationally defined requirements for information on the label may influence the label size. Additional labeling requirements for banked products of human milk origin are provided in *ISBT 128 Standard Labeling of Human Milk Banking Products* (ST-013).

Example Label 4.5cm x 4.5cm

Example Label 7.5cm x 5cm

A9999 24 000001 25 5
Split No: 13
Product Code: M0001013

Human Milk Pasteurized

For Nutritional Use

Store at or below -30C

Expires on 01 JAN 2025

Use within 24 hours of thawing

Below are images of banked human milk labels generously provided by the Greater Glasgow and Clyde Milk Bank in Scotland. These pictures serve as an example of how ISBT 128 has been implemented for use in labeling banked human milk.

8 The Role of Technical Advisory Groups

ICCBBA involves international volunteer experts in various MPHO fields to further develop and maintain the Standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly (through conference calls, face-to-face meetings, and asynchronous discussion forums) to further develop and expand the Standard ensuring it continues to meet the needs of its users. The vital role of these groups cannot be overemphasized. It is only through the involvement of such expert panels that ICCBBA can be assured it has the knowledge base to anticipate the needs of its users in fields where change is constant. More than 300 experts participate in the ICCBBA TAGs.

In order to ensure a common approach to the identification, the Milk Banking Technical Advisory Group (MBTAG) was established in 2013. The advisory group is supported by the European Milk Bank Association (EMBA) and the Human Milk Banking Association of North America (HMBANA).

9 The Role of ICCBBA

ICCBBA is the not-for-profit international non-state actor that maintains, develops, and licenses ISBT 128, the international information standard for the terminology, coding, and labeling of medical products of human origin. It maintains a permanent office to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports the Technical Advisory Groups that include experts from both the transfusion/transplantation community and relevant manufacturers. Fees collected by ICCBBA from registered facilities are used to support these functions.

Through its activities, ICCBBA provides the management support essential to sustain standard coding in human milk banking. In particular, it delivers:

1) Stability – users can be confident in the stability of the Standard to satisfy the long time periods over which information has to be retained;
2) User focus – the user community are the experts in their field and ICCBBA, through its Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs;
3) Flexibility – as clinical and scientific knowledge grows there is rapid development with changing information needs. ICCBBA ensures that the Standard is flexible enough to accommodate those needs;
4) Responsiveness – in these rapidly developing medical fields ICCBBA ensures that the Standard is able to respond to user needs in a timely manner;
5) Globalization – ISBT 128 is an international standard with endorsement worldwide;
6) Compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility.

MPHO collection and processing facilities, and manufacturers of equipment or software that use ISBT 128, are required to register with ICCBBA and pay a registration and annual license fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA website at www.isbt128.org, email our help desk at support@isbt128.org; or call us at +1 909 793 6516.

END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin
ST-013 ISBT 128 Standard Labeling of Human Milk Banking Products
ST-020 ISBT 128 Standard for XML
ST-026 ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier
ST-027 ISBT 128 Dictionary of Standard Data Elements

